

<b>Interview Summary</b>	Application No. 10/780,296	Applicant(s) WILSON ET AL.	
	Examiner Mark L. Berch	Art Unit 1624	

All participants (applicant, applicant's representative, PTO personnel):

- (1) Mark L. Berch. (3) \_\_\_\_\_  
 (2) Jeffrey Childers. (4) \_\_\_\_\_

Date of Interview: 20 October 2006.

Type: a) ☒ Telephonic b) ☐ Video Conference  
 c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.  
 If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: All.

Identification of prior art discussed: \_\_\_\_\_.

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Proposed fax amendment reviewed. It would overcome all rejections. Several species in Claim 17 has "sulfonyl" and it would be likely that sulfo was actually intended.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

  
 Examiner's signature, if required

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

#### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

**Confidentiality Note:**

The information contained in this facsimile message is confidential and its contents are intended to be legally privileged information solely for the use of the addressee. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution, copying or other use of this message and its contents is strictly prohibited. If you have received this facsimile in error, please notify us immediately by telephone and return the original message to us at the address shown below via air courier service, the United States Postal Service or your national postal service (air mail). Thank You.

**ALSTON & BIRD LLP**

3201 Beechleaf Court, Suite 600  
Raleigh, NC 27604-1062

919-862-2200  
Fax: 919-862-2260

**TELECOPY**

**PLEASE DELIVER AS SOON AS POSSIBLE**

**DATE:** October 19, 2006

**TO:** TC 1600

**FROM:** Jeffrey W. Childers, Ph.D.

**Appl. No.:** 10/780,296

**Confirmation No.:** 9724

**Applicant(s):** Wilson *et al.*

**Filed:** 2/17/04

**Art Unit:** 1624

**Examiner:** M. Berch

**Title:** A1 ADENOSINE RECEPTOR ANTAGONISTS

**Attachments**

Examiner Interview Request(1 page)

Draft Amendment(14 pages)

**NO. OF PAGES:** 16  
(Including cover page)

**OPERATOR:**

**IF NOT RECEIVED PROPERLY, PLEASE NOTIFY ME IMMEDIATELY AT (919) 862-2200**

**USER CODE:** LAKE

**FAX NUMBER:** 571-273-0663

**CLIENT/MATTER:** 049542/283879

**REQUESTED BY:** Pam Lockley

**VOICE NUMBER:**

PTOL-413A (12-02)

Approved for use through xx/xx/xxxx OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

**Applicant Initiated Interview Request Form**Application No.: 10/780,296  
Examiner: Mark BerchFirst Named Applicant: Wilson *et al.*  
Art Unit: 1624 Status of Application: Pending**Tentative Participants:**

(1) Jeffrey W. Childers

(2) Examiner Mark L. Berch

(3)

(4)

Proposed Date of Interview: 10/20/06 Proposed Time: 11:30 (AM)

**Type of Interview Requested:**(1) ☒ Telephonic (2) ☐ Personal (3) ☐ Video ConferenceExhibit To Be Shown or Demonstrated: ☐ YES ☐ NO

If yes, provide brief description:

**Issues To Be Discussed**

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1) 112, 2nd ¶	1-4, 12-14, 18		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(2) 112, 1st ¶	1-7, 12-16, 18		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(3) 112, 1st ¶	1-8, 12-18		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(4) Double Patenting	1-8, 12-18		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Continuation Sheet Attached**Brief Description of Arguments to be Presented:**Applicants submit that proposed claim amendments put claims in condition for allowance and respectfully request the same.

An interview was conducted on the above-identified application on \_\_\_\_\_.

**NOTE:**

This form should be completed by applicant and submitted to the examiner in advance of the interview (see MPEP § 713.01).

This application will not be delayed from issue because of applicant's failure to submit a written record of this interview. Therefore, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible.

(Applicant/Applicant's Representative Signature)  
LEGAL01/13023102v1

(Examiner/SPE Signature)

**DRAFT  
PATENT**

**FOR PURPOSES OF INTERVIEW ONLY**  
**DO NOT ENTER**

**RESPONSE UNDER 37 C.F.R. 1.116 - EXPEDITED  
PROCEDURE - EXAMINING GROUP 1624**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appl. No.:	10/780,296	Confirmation No.:	9724
Applicant(s):	Wilson et al.		
Filed:	February 17, 2004		
Art Unit:	1624		
Examiner:	Berch, Mark L.		
Title:	A <sub>1</sub> ADENOSINE RECEPTOR ANTAGONISTS		

Docket No.: 5623-13 (049542/283879)  
Customer No.: 00826

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**AMENDMENT AFTER FINAL UNDER 37 CFR § 1.116**

Sir:

In response to the Final Office Action dated July 20, 2006, please amend the above-identified application as follows:

**Amendments to the Claims** are reflected in the listing of claims beginning on page 2 of this paper.

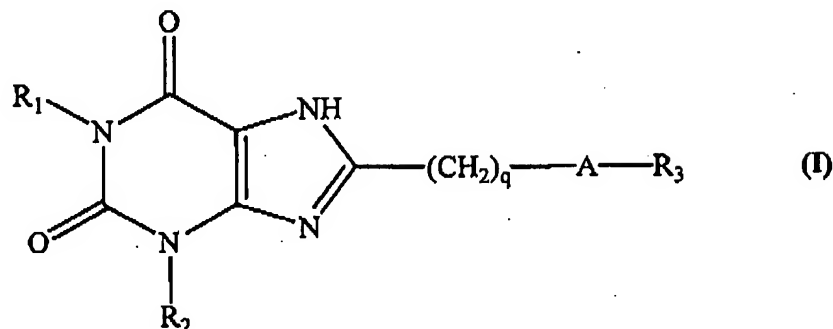
**Remarks/Arguments** begin on page 9 of this paper.

Appl. No.: 10/780,296  
 Amdt. dated 10/03/2006  
 Reply to Office action of July 20, 2006

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Amendments to the Claims:

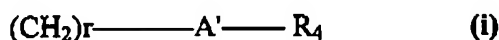
1. (Currently amended) A compound of formula (I):



wherein:

A is a 5- or 6-membered heteroaromatic ring containing 1 to 4 heteroatoms selected from the group consisting of N, O, and S;

R<sub>2</sub> is of the formula (i):



wherein:

A' is a 6-membered aromatic ring or heteroaromatic ring containing ~~[[0]]~~ 1 to 4 nitrogen atoms ~~heteroatoms selected from the group consisting of N, O, and S;~~

r is an integer ranging from 1 to 20;

R<sub>4</sub> is selected from the group consisting of H; NH<sub>2</sub>; (CH<sub>2</sub>)<sub>s</sub>OH, wherein s is an integer ranging from 1 to 8; [[COOH;]] R<sub>14</sub>COOH, wherein R<sub>14</sub> is an alkylene or alkylidene group having 1 to 8 carbon atoms; halo, NHR<sub>8</sub>, NR<sub>8</sub>R<sub>9</sub>, NHCOR<sub>8</sub>, NR<sub>8</sub>COR<sub>9</sub>, SO<sub>3</sub>H and PO<sub>3</sub>H<sub>2</sub>;

R<sub>3</sub> is selected from the group consisting of H, NH<sub>2</sub>, R<sub>15</sub>COOH, wherein R<sub>15</sub> is an alkylene or alkylidene group having 1 to 8 carbon atoms, and (CH<sub>2</sub>)<sub>t</sub>OH, wherein t is an integer ranging from 1 to 8; halo, NHR<sub>8</sub>, NR<sub>8</sub>R<sub>9</sub>, NHCOR<sub>8</sub>, NR<sub>8</sub>COR<sub>9</sub>, SO<sub>3</sub>H and PO<sub>3</sub>H<sub>2</sub>;

Appl. No.: 10/780,296  
 Amdt. dated 10/03/2006  
 Reply to Office action of July 20, 2006

DRAFT

q is an integer ranging from 1 to 8; and

R<sub>1</sub> is a C<sub>1</sub>-C<sub>8</sub> alkanyl group, C<sub>2</sub>-C<sub>8</sub>-alkenyl- or C<sub>2</sub>-C<sub>8</sub>-alkynyl- group which is optionally substituted by -CN, -CH<sub>2</sub>NR<sub>6</sub>R<sub>7</sub>OH, -OR<sub>8</sub>, -NR<sub>6</sub>R<sub>7</sub>, -NHCOR<sub>8</sub>, NHCONR<sub>6</sub>R<sub>7</sub>, halogen, -OCOR<sub>8</sub>, -OCH<sub>2</sub>COOH, -OCH<sub>2</sub>COOR<sub>8</sub>, -SO<sub>2</sub>R<sub>5</sub>, -S-R<sub>5</sub>, -OCH<sub>2</sub>-CONR<sub>6</sub>R<sub>7</sub>, -OCH<sub>2</sub>CH<sub>2</sub>OH, -SO<sub>2</sub>-CH<sub>2</sub>-CH<sub>2</sub>-O-COR<sub>8</sub>, -OCH<sub>2</sub>CH<sub>2</sub>-NR<sub>6</sub>R<sub>7</sub>, -SO<sub>2</sub>-CH<sub>2</sub>-CH<sub>2</sub>-OH, -CONHSO<sub>2</sub>R<sub>8</sub>, -CH<sub>2</sub>CONHSO<sub>2</sub>R<sub>8</sub>, -OCH<sub>2</sub>CH<sub>2</sub>OR<sub>8</sub>, -COOH, --COOR<sub>8</sub>, -CONR<sub>6</sub>R<sub>7</sub>, -CHO, -SR<sub>8</sub>, -SOR<sub>8</sub>, -SO<sub>2</sub>R<sub>8</sub>, -SO<sub>3</sub>H, -PO<sub>3</sub>H<sub>2</sub>, -SO<sub>2</sub>NR<sub>6</sub>R<sub>7</sub>, -OCH<sub>2</sub>-CH<sub>2</sub>OCOR<sub>8</sub>, -CH=NOH, -CH=NOR<sub>8</sub>, -COR<sub>9</sub>, -CH(OH)R<sub>9</sub>, -CH(OR<sub>8</sub>)<sub>2</sub>, -CH=CH-R<sub>10</sub>, -OCONR<sub>6</sub>R<sub>7</sub>,

R<sub>5</sub> is C<sub>1</sub>-C<sub>4</sub>-alkyl, optionally substituted by OH, OCOR<sub>8</sub>, NH<sub>2</sub>, NR<sub>6</sub>R<sub>7</sub> or NHCOR<sub>8</sub>.

R<sub>6</sub>[[,] and ~~R<sub>7</sub> and R<sub>8</sub>~~ are each independently hydrogen, an optionally substituted C<sub>3</sub>-6-cycloalkyl group, a branched or unbranched alkyl-, alkenyl- or alkynyl group having up to 10 carbon atoms, which may optionally be substituted by hydroxy, phenyl, substituted phenyl, amino, ~~amino-substituted with C<sub>1</sub>-to-C<sub>8</sub> alkyl~~, or it denotes -(CH<sub>2</sub>)<sub>m</sub>-NHCOOR<sub>8</sub> wherein m=1, 2, 3 or 4;

R<sub>8</sub> is hydrogen, C<sub>1</sub>-C<sub>8</sub>-alkyl or C<sub>2</sub>-C<sub>8</sub>-alkenyl or C<sub>2</sub>-C<sub>8</sub>-alkynyl optionally substituted with CO<sub>2</sub>H, a benzyl- or phenyl- group, which is optionally mono- or polysubstituted by OCH<sub>3</sub>;

R<sub>9</sub> is C<sub>1</sub>-C<sub>8</sub>-alkyl or C<sub>2</sub>-C<sub>8</sub>-alkenyl or C<sub>2</sub>-C<sub>8</sub>-alkynyl optionally substituted with CO<sub>2</sub>H, optionally substituted phenyl, optionally substituted benzyl, C<sub>3</sub>-C<sub>6</sub>-cycloalkyl, and

R<sub>10</sub> is -COOR<sub>8</sub>, -CH<sub>2</sub>OR<sub>8</sub>, -CONR<sub>6</sub>R<sub>7</sub>, hydrogen, C<sub>1</sub>-C<sub>3</sub>-alkyl, optionally substituted phenyl, -CH<sub>2</sub>NR<sub>6</sub>R<sub>7</sub>;

and pharmaceutically acceptable salts, hydrates and prodrugs thereof.

2. (Original) The compound of claim 1, wherein at least one of R<sub>3</sub> and R<sub>4</sub> is independently selected from the group consisting of SO<sub>3</sub>H and PO<sub>3</sub>H<sub>2</sub>.

3. (Previously presented) The compound of claim 1, wherein R<sub>1</sub> is a C<sub>1</sub>-C<sub>8</sub> alkanyl group, C<sub>2</sub>-C<sub>8</sub>-alkenyl group or C<sub>2</sub>-C<sub>8</sub> alkynyl group which is optionally substituted by NR<sub>6</sub>R<sub>7</sub>, -SO<sub>3</sub>H, or -PO<sub>3</sub>H<sub>2</sub>.

Appl. No.: 10/780,296  
Amdt. dated 10/03/2006  
Reply to Office action of July 20, 2006

DRAFT

4. (Previously presented) The compound of claim 1, wherein A is selected from the group selected from the group consisting of pyridyl, thiophenyl, thiazolyl, and tetrazolyl.

5. (Original) The compound of claim 1, wherein A' is phenyl.

6. (Previously presented) The compound of claim 1, wherein:  
R<sub>1</sub> is a C<sub>1</sub>-C<sub>8</sub> alkanyl group, C<sub>2</sub>-C<sub>8</sub>-alkenyl group or C<sub>2</sub>-C<sub>8</sub> alkynyl group which is optionally substituted by NR<sub>6</sub>R<sub>7</sub> or -SO<sub>3</sub>H;  
A is selected from the group selected from the group consisting of pyridyl, thiophenyl, thiazolyl, and tetrazolyl; and  
A' is phenyl.

7. (Original) The compound of claim 6, wherein at least one of R<sub>3</sub> and R<sub>4</sub> is independently selected from the group consisting of SO<sub>3</sub>H and PO<sub>3</sub>H<sub>2</sub>.

8. (Currently amended) The compound of claim 1, wherein said compound is selected from the group consisting of:

3-[2-(4-Aminophenyl)ethyl]-1-propyl-8-[(3-pyridyl)methyl]xanthine;  
3-[2-(4-Aminophenyl)ethyl]-1-propyl-8-[(4-thiazolyl)methyl]xanthine;  
3-[2-(4-Aminophenyl)ethyl]-1-propyl-8-[(thiophen-2-yl)methyl]xanthine;  
3-[2-(4-Aminophenyl)ethyl]-1-propyl-8-[(1H-tetrazol-5-yl)methyl]xanthine;  
and pharmaceutically acceptable salts, ~~hydrates~~ and prodrugs thereof.

9-11. (Canceled)

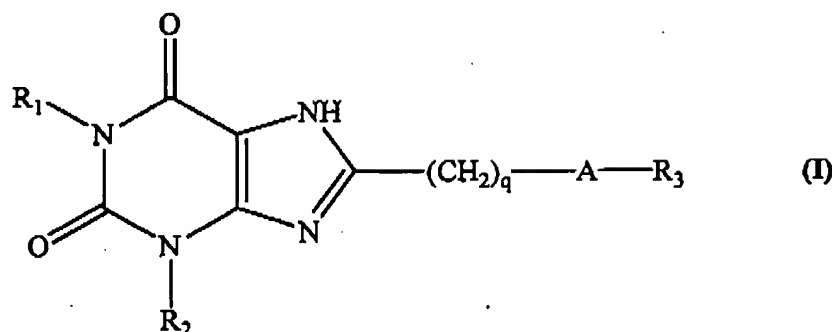
12. (Original) A composition comprising a compound of claim 1 in a pharmaceutically acceptable carrier.

13. (Currently amended) A compound of formula (I):



Appl. No.: 10/780,296  
 Arndt. dated 10/03/2006  
 Reply to Office action of July 20, 2006

DRAFT



wherein:

A is a 5- or 6-membered aromatic ring;

R<sub>2</sub> is of the formula (i):



wherein:

A' is a 6-membered aromatic ring or a heteroaromatic ring containing [[0]] 1 to 4 nitrogen atoms ~~heteroatoms selected from the group consisting of N, O, and S;~~

r is an integer ranging from 1 to 20;

R<sub>4</sub> is selected from the group consisting of NH<sub>2</sub>, halo, NHR<sub>8</sub>, NR<sub>8</sub>R<sub>9</sub>, NHCOR<sub>8</sub>, NR<sub>8</sub>COR<sub>9</sub>, [[COOH,]] SO<sub>3</sub>H and PO<sub>3</sub>H<sub>2</sub>;

R<sub>3</sub> is selected from the group consisting of H, NH<sub>2</sub>, R<sub>15</sub>COOH, wherein R<sub>15</sub> is an alkylene or alkylidene group having 1 to 8 carbon atoms, and (CH<sub>2</sub>)<sub>t</sub>OH, wherein t is an integer ranging from 1 to 8; halo, NHR<sub>8</sub>, NR<sub>8</sub>R<sub>9</sub>, NHCOR<sub>8</sub>, NR<sub>8</sub>COR<sub>9</sub>, SO<sub>3</sub>H and PO<sub>3</sub>H<sub>2</sub>;

q is an integer ranging from 1 to 8; and

R<sub>1</sub> is a C<sub>1</sub>-C<sub>8</sub> alkanyl- group, C<sub>2</sub>-C<sub>8</sub>-alkenyl-, or C<sub>2</sub>-C<sub>8</sub>-alkynyl- group which is optionally substituted by -CN, -CH<sub>2</sub>NR<sub>6</sub>R<sub>7</sub>OH, -OR<sub>8</sub>, -NR<sub>6</sub>R<sub>7</sub>, -NHCOR<sub>8</sub>, -NHCONR<sub>6</sub>R<sub>7</sub>, halogen, -OCOR<sub>8</sub>, -OCH<sub>2</sub>COOH, -OCH<sub>2</sub>COOR<sub>8</sub>, -SO<sub>2</sub>R<sub>5</sub>, -S-R<sub>5</sub>, -OCH<sub>2</sub>-CONR<sub>6</sub>R<sub>7</sub>, -OCH<sub>2</sub>CH<sub>2</sub>OH, -SO<sub>2</sub>-CH<sub>2</sub>-CH<sub>2</sub>-O-COR<sub>8</sub>, -OCH<sub>2</sub>-CH<sub>2</sub>-NR<sub>6</sub>R<sub>7</sub>, -SO<sub>2</sub>-CH<sub>2</sub>-CH<sub>2</sub>-OH, -CONHSO<sub>2</sub>R<sub>8</sub>, -CH<sub>2</sub>CONHSO<sub>2</sub>R<sub>8</sub>, -OCH<sub>2</sub>CH<sub>2</sub>OR<sub>8</sub>, -COOH, -COOR<sub>8</sub>, -CONR<sub>6</sub>R<sub>7</sub>, -CHO, -SR<sub>8</sub>, -SOR<sub>8</sub>, -SO<sub>2</sub>R<sub>8</sub>,

DRAFT

Appl. No.: 10/780,296

Amdt. dated 10/03/2006

Reply to Office action of July 20, 2006

-SO<sub>3</sub>H, -PO<sub>3</sub>H<sub>2</sub>, -SO<sub>2</sub>NR<sub>6</sub>R<sub>7</sub>, -OCH<sub>2</sub>-CH<sub>2</sub>OCOR<sub>8</sub>, -CH=NOH, -CH=NOR<sub>8</sub>, -COR<sub>9</sub>, -CH(OH)R<sub>9</sub>,  
-CH(OR<sub>8</sub>)<sub>2</sub>, -CH=CH-R<sub>10</sub>, -OCONR<sub>6</sub>R<sub>7</sub>,

R<sub>5</sub> is C<sub>1</sub>-C<sub>4</sub>-alkyl, optionally substituted by OH, OCOR<sub>8</sub>, NH<sub>2</sub>, NR<sub>6</sub>R<sub>7</sub> or NHCOR<sub>8</sub>,

R<sub>6</sub> and R<sub>7</sub> [[- R<sub>8</sub>]] are each independently hydrogen, an optionally substituted C<sub>3-6</sub>-cycloalkyl group, a branched or unbranched alkyl-, alkenyl- or alkynyl group having up to 10 carbon atoms, which may optionally be substituted by hydroxy, phenyl, substituted phenyl, amino, ~~amino-substituted with C<sub>1</sub>-C<sub>8</sub>-alkyl~~, or it denotes -(CH<sub>2</sub>)<sub>m</sub>-NHCOOR<sub>8</sub> wherein m=1, 2, 3 or 4;

R<sub>8</sub> is hydrogen, C<sub>1</sub>-C<sub>8</sub>-alkyl or C<sub>2</sub>-C<sub>8</sub>-alkenyl or C<sub>2</sub>-C<sub>8</sub>-alkynyl optionally substituted with CO<sub>2</sub>H, a benzyl- or phenyl- group, which is optionally mono- or polysubstituted by OCH<sub>3</sub>;

R<sub>9</sub> is C<sub>1</sub>-C<sub>8</sub>-alkyl or C<sub>2</sub>-C<sub>8</sub>-alkenyl or C<sub>2</sub>-C<sub>8</sub>-alkynyl optionally substituted with CO<sub>2</sub>H, optionally substituted phenyl, optionally substituted benzyl, C<sub>3</sub>-C<sub>6</sub>-cycloalkyl, and

R<sub>10</sub> is -COOR<sub>8</sub>, -CH<sub>2</sub>OR<sub>8</sub>, -CONR<sub>6</sub>R<sub>7</sub>, hydrogen, C<sub>1</sub>-C<sub>3</sub>-alkyl, optionally substituted phenyl, -CH<sub>2</sub>NR<sub>6</sub>R<sub>7</sub>;

and pharmaceutically acceptable salts, hydrates, and prodrugs thereof.

14. (Previously presented) The compound of claim 13, wherein A is phenyl.

15. (Previously presented) The compound of claim 13, wherein A' is phenyl.

16. (Currently amended) The compound of claim 13, wherein:

A is phenyl;

A' is phenyl;

r is 2;

R<sub>4</sub> is selected from the group consisting of NH<sub>2</sub>, [[COOH]], NHCOR<sub>8</sub>,  
and SO<sub>3</sub>H;

R<sub>3</sub> is selected from the group consisting of H, NH<sub>2</sub>, halo, SO<sub>3</sub>H, and  
NHCOR<sub>8</sub>;

q is 1; and

Appl. No.: 10/780,296  
Amdt. dated 10/03/2006  
Reply to Office action of July 20, 2006

DRAFT

$R_1$  is a  $C_1$ - $C_8$  alkanyl group optionally substituted by  $-OR_6$ ,  $-NR_6R_7$ ,  
or  $-SO_3H$ .

17. (Currently amended) The compound of claim 13, wherein said compound is selected from the group consisting of:

3-[2-(4-Aminophenyl)ethyl]-8-benzyl-1-propylxanthine;  
3-[2-(4-Aminophenyl)ethyl]-1-propyl-8-(4-sulfonoxybenzyl)xanthine;  
3-[2-(4-Aminophenyl)ethyl]-8-benzyl-1-(3-methoxypropyl)xanthine;  
3-[2-(4-Aminophenyl)ethyl]-8-benzyl-1-(3-dimethylamino)propylxanthine;  
3-[2-[4-(6-Aminohexanoyl)aminophenyl]ethyl]-8-benzyl-1-propylxanthine;  
8-Benzyl-1-propyl-3-[4-(4-sulfonoxyphenyl)butyl]xanthine;  
8-Benzyl-1-propyl-3-[2-(4-sulfonoxyphenyl)ethyl]xanthine;  
3-[2-(4-Aminophenyl)ethyl]-8-benzyl-1-(3-sulfonoxypropyl)xanthine;  
3-[2-(4-Aminophenyl)ethyl]-8-(4-fluorobenzyl)-1-propylxanthine;  
8-(2-Acetaminobenzyl)-3-[2-(4-aminophenyl)ethyl]-1-propylxanthine;  
8-(2-Aminobenzyl)-3-(2-phenylethyl)-1-propylxanthine;  
~~8-Benzyl-3-[2-(3-carboxyphenyl)ethyl]-1-propylxanthine;~~  
3-[2-(4-Aminophenyl)ethyl]-8-benzyl-1-(8-sulfonooctyl)xanthine;  
3-[2-(4-Aminophenyl)ethyl]-8-benzyl-1-(5-sulfonoxypentyl)xanthine;  
3-[2-(4-Aminophenyl)ethyl]-8-benzyl-1-(5-sulfonoxypentyl)xanthine; and  
pharmaceutically acceptable salts, hydrates and prodrugs thereof.

18. (Previously presented) A composition comprising a compound of claim 13 in a pharmaceutically acceptable carrier.

19. (New) A compound selected from the group consisting of:

8-Benzyl-3-[2-(3-carboxyphenyl)ethyl]-1-propylxanthine;  
3-[2-(2-carboxyphenyl)ethyl]-8-(3-fluorobenzyl)-1-propylxanthine;  
3-[2-(2-carboxyphenyl)ethyl]-8-(3-nitrobenzyl)-1-propylxanthine;

Appl. No.: 10/780,296  
Amdt. dated 10/03/2006  
Reply to Office action of July 20, 2006

**DRAFT**

3-[2-(2-carboxyphenyl)ethyl]-1-propyl-8-[(2-pyridyl)methyl]xanthine; and  
3-[2-(2-carboxyphenyl)ethyl]-1-propyl-8-[(2-pyridyl)methyl]xanthine;  
and pharmaceutically acceptable salts and prodrugs thereof.

20. (New) A composition comprising a compound of claim 19 in a pharmaceutically acceptable carrier.

Appl. No.: 10/780,296  
Amdt. dated 10/03/2006  
Reply to Office action of July 20, 2006

DRAFT

**REMARKS/ARGUMENTS**

Claims 1-8 and 12-18 are pending in the subject application. Claims 1-8 and 12-18 presently stand rejected. Claims 1, 8, 13, 16, and 17 have been amended by the present amendment. New claims 19 and 20 have been added by the present amendment. No new matter is added. Therefore, upon entry of the present amendment, claims 1-8 and 12-20 will remain pending in the subject application. Reexamination and reconsideration of the claims are respectfully requested in view of these amendments and the following remarks. The Examiner's comments in the Office Action are addressed below in the order set forth therein.

**The Rejection of Claims 1-4, 12-14, and 18 under 35 U.S.C. § 112, Second Paragraph,  
Should Be Withdrawn**

Claims 1-4, 12-14, and 18 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More particularly, the Office Action asserts that in the A' definition in claim 1, O and S are now impossible because a 6-membered heteroaromatic ring cannot contain either O or S.

Applicants have amended claim 1 and claim 13 by removing O and S from the definition of A' and by clarifying that A' can be a 6-membered aromatic ring or a heteroaromatic ring containing 1 to 4 nitrogen atoms. Applicants respectfully submit that claim 1 and claim 13 are in condition for allowance and respectfully request the same. Claims 2-4, and 12 depend from claim 1, and claims 14 and 18 depend from claim 13. Because claims 1 and 13 are believed to be in condition for allowance, dependent claims 2-4, 12, 14 and 18 also are believed to be in condition for allowance and Applicants respectfully request the same.

**The Rejection of Claims 1-7, 12-16, and 18 under 35 U.S.C. § 112, First Paragraph,  
Should Be Withdrawn**

Claims 1-7, 12-16, and 18 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office Action lists four

Appl. No.: 10/780,296  
Amdt. dated 10/03/2006  
Reply to Office action of July 20, 2006

DRAFT

points (A-D) for rejecting the claims. Each point is addressed below in the order it appears in the Office Action:

A. The Office Action asserts that the removal of "it denotes" from the  $R_6$  definition introduces new matter by changing its role. Applicants have amended claim 1 and claim 13 by inserting the phrase "it denotes" immediately preceding the term " $-(CH_2)_m-NHCOOR_6$ ." The portion of claim 1 in question has now been returned to its original form and claim 13 has been amended to be consistent with the language of claim 1 as originally filed. Accordingly, Applicants submit that the present amendment renders moot the rejection of claim 1 and claim 13 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement and respectfully request that the rejection of claim 1 and claim 13 as it relates to the phrase "it denotes" be withdrawn at this time.

B. The Office Action asserts that the amino substituted by  $C_{1-8}$  is new matter. Applicants have amended claim 1 and claim 13 by deleting the reference to "amino substituted with  $C_1-C_8$  alkyl...." Applicants submit that the present amendments render moot the rejection of claim 1 and claim 13 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement and respectfully request that the rejection of claim 1 and claim 13 as it relates to the phrase "amino substituted with  $C_1-C_8$  alkyl" be withdrawn at this time.

C. The Office Action asserts that the inclusion of  $R_8$  into the definition list for  $R_6$  expands the definition of  $R_6$  and allegedly is new matter. Applicants have amended claim 1 and claim 13 by defining  $R_8$  as it was defined in the claims as originally filed. Support for this amendment can be found on page 9 of the application as filed and in original claim 1. No new matter has been added. Applicants respectfully submit that the present amendments render moot the rejection of claims 1 and 13 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement and respectfully request that the rejection of claim 1 and claim 13 as it relates to the definition of  $R_8$  be withdrawn at this time.

Appl. No.: 10/780,296  
Amndt. dated 10/03/2006  
Reply to Office action of July 20, 2006

DRAFT

D. The Office Action asserts that the new choice of R<sub>4</sub> as COOH is allegedly new matter. Without acquiescing to the Examiner's comments, Applicants have amended claims 1, 13, and 16 by deleting the variable "COOH" from the definition of R<sub>4</sub> therein. Applicants also have amended claim 17 by deleting reference to the compound named 8-benzyl-3-[2-(3-carboxyphenyl)ethyl]-1-propylxanthine, in which R<sub>4</sub> is COOH. Accordingly, Applicants submit that the present amendments render moot the rejection of claims 1, 13, and 16 as allegedly failing to comply with the written description requirement and respectfully request that the rejection of claims 1, 13, and 16 as it relates to the choice of R<sub>4</sub> as COOH be withdrawn at this time.

Applicants submit that claims 1, 13, 16, and 17 as currently amended are in condition for allowance and respectfully request the same. Because claims 1 and 13 are believed to be in condition for allowance, dependent claims 2-7, 12, 14-15, which depend from claims 1 and 13, also are believed to be in condition for allowance and Applicants respectfully request the same.

The Rejection of Claims 1-8 and 12-18 under 35 U.S.C. § 112, First Paragraph,  
Should Be Withdrawn

Claims 1-8 and 12-18 have been rejected under 35 U.S.C. § 112, first paragraph, under the contention that the specification allegedly does not provide enablement for hydrates. Without acquiescing to the Patent Office's contention, Applicants have amended claims 1, 8, 13, and 17 by deleting the term "hydrates" therefrom. Applicants reserve the rights to file one or more continuation applications directed to the subject matter deleted from claims 1, 8, 13, and 17. Applicants respectfully submit that the present amendments render moot the rejection of claims 1-8 and 12-18 under 35 U.S.C. § 112, first paragraph, under the contention that the specification allegedly does not provide enablement for hydrates and request that this rejection be withdrawn.

Appl. No.: 10/780,296  
Amdt. dated 10/03/2006  
Reply to Office action of July 20, 2006

DRAFT

The Provisional Rejection of Claims 1-8 and 12-18 for Double Patenting  
Should Be Withdrawn

Claims 1-8 and 12-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending application serial no. 10/861,677 (hereinafter "the '677 application") for the reasons stated in the Office Action. Without acquiescing to the grounds of the double patenting rejection, Applicants note that the copending applications are still in the process of examination. Thus, it is not yet known which of these applications will be the first to be allowed for issuance as a patent. Should the copending '677 application be the first to be in condition for allowance, Applicants will, upon notification to this effect, either argue the double-patenting rejection or timely file a terminal disclaimer in the present application. Applicants therefore respectfully submit that they have responded appropriately to this provisional rejection and request that this rejection be withdrawn at this time.

New Claims

New claims 19 and 20 have been added by the present amendment. New claims 19 and 20 are directed to the compound 8-benzyl-3-[2-(3-carboxyphenyl)ethyl]-1-propylxanthine; 3-[2-(2-carboxyphenyl)ethyl]-8-(3-fluorobenzyl)-1-propylxanthine; 3-[2-(2-carboxyphenyl)ethyl]-8-(3-nitrobenzyl)-1-propylxanthine; 3-[2-(2-carboxyphenyl)ethyl]-1-propyl-8-[(2-pyridyl)methyl]xanthine; and 3-[2-(2-carboxyphenyl)ethyl]-1-propyl-8-[(2-pyridyl)methyl]xanthine and a composition of said compounds in a pharmaceutically acceptable carrier, respectively. Support for new claims 19 and 20 can be found in pages 11-12, and Example 12, pages 27-28, of the application as filed and in original claims 9 and 12. No new matter has been added. Applicants submit that new claims 19 and 20 are in condition for allowance and respectfully request the same.



Appl. No.: 10/780,296  
Amdt. dated 10/03/2006  
Reply to Office action of July 20, 2006

**DRAFT**

**CONCLUSION**

In view of the aforementioned amendments and remarks, Applicants respectfully submit that the rejections of the claims under 35 U.S.C. §112, first paragraph, and §112, second paragraph, are now overcome. Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

**DRAFT**

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Appl. No.: 10/780,296  
Amdt. dated 10/03/2006  
Reply to Office action of July 20, 2006

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